IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9013

Bartle, J. February 28, 2013

Carol S. Barber ("Ms. Barber" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. William H. Barber, Ms. Barber's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In March, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Robert N. Notske, M.D., F.A.C.C., F.A.C.P. Dr. Notske is no stranger to this litigation. According to the Trust, he has signed at least 45 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated October 10, 2002, Dr. Notske attested in Part II of Ms. Barber's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial

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3. (...continued)
presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

dimension, and a reduced ejection fraction in the range of 50% to 60%.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $415,893.[5]

In the report of claimant's echocardiogram, the reviewing cardiologist, Douglas E. Brown, M.D., stated that claimant had "mild mitral regurgitation (1+)." Dr. Brown, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In October, 2005, the Trust forwarded the claim for review by Henryk Kafka, C.D., B.A., M.D., F.R.C.P.C., F.A.C.P., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Kafka concluded that there was no reasonable medical basis for Dr. Notske's finding that claimant had moderate mitral

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4. Dr. Notske also attested that claimant suffered from mild aortic regurgitation and New York Heart Association Functional Class II symptoms. These conditions are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's findings of a reduced ejection fraction and an abnormal left atrial dimension, each of which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Kafka stated:

> There is a bright signal in the [left atrium] very early in the cycle. It [can] be seen at the R wave and is gone in two frames or fewer, to be followed by a second jet that does represent [mitral regurgitation]. The fact that the large early jet is not true [mitral regurgitation] is evidenced in one [of] the partial 5 chamber color flow maps. This shows the simultaneous appearance of definite aortic regurgitation and this blue jet in the [left atrium]. This cannot be true [mitral regurgitation]. I have measured the size of the later signal. It is at its largest in the 2 chamber view. RJA is 2.9. LAA at endsystole [sic] on the view is 22. The ratio is less than 20%.

Based on Dr. Kafka's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Barber's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[6] In contest, claimant submitted a declaration from Dr. Notske wherein he confirmed his finding of moderate mitral regurgitation. In support of his finding, Dr. Notske explained:

> 22. The auditing cardiologist cites no violation of either the Feigenbaum or Weyman

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Barber's claim.

texts regarding my interpretation of the echocardiogram. To the contrary, my opinion is supported by Professors Feigenbaum and Weyman.

23. Professor Harvey Feigenbaum in his textbook, *Echocardiography* (5th ed. 1994), finds that the "most common approach for using color flow Doppler to quantitate mitral regurgitation is to measure the area of the maximum regurgitant jet and to compare that value as a ratio to the area of the left atrium." Feigenbaum, at 252, 253. Feigenbaum acknowledges the limitations to this approach in his textbook, and then goes on to say that "to meet the criteria for measuring the regurgitant area, one probably should take the **maximum turbulent flow area**." *Id.*, at p. 253 (emphasis added).

24. Similarly, Professor Arthur Weyman's, *Principles and Practice of Echocardiography* (2d ed. 1994) remarks that:

> The regurgitant jets encountered clinically are dynamic three-dimensional structures that can change size, shape, and direction during systole. Thus, some fixed parameter must be defined to represent the dynamic jet or jet area continuously recorded throughout systole and averaged or integrated over time. Generally, the maximum jet area occurring **at any point** during systole is taken as the representative value.... Once the plane containing the greatest jet length/area is identified, the maximal jet area **in any frame** is planimetered.

Weyman, at 435 (emphasis added).

25. In addition to the quote from Professor Weyman set forth above, Professor Feigenbaum in his textbook states that "[w]ith regard to transthoracic echoes, the interpreting cardiologist should take into account the **entire regurgitant jet, including the**

surrounding lower flow spray." Feigenbaum, at 253 (emphasis added).

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27. My finding of moderate mitral regurgitation is not based upon the frames viewed by the auditing cardiologist. It appears that the frames to which the auditing cardiologist refers are at 09:34:58. Let me discuss what is taking place in those frames:

First, in the frames that begin with 09:34:58 there is aortic regurgitation that begins in early diastole and extends into the very earliest portion of systole. The view demonstrates that the pressure was higher in the aorta at this time and that there is an abnormality of the aortic valve so that it cannot prevent blood from returning to the Left Ventricle after it has been ejected into the Aorta. Second, the phenomenon demonstrated in these frames is very late diastolic Mitral regurgitation, as well as systolic Mitral regurgitation. It demonstrates that a small amount of blood passed into the left Atrium during late diastole and an even greater amount passed backward into the Left Atrium during systole.

Second, the unusual prolonged Aortic regurgitation and the late diastolic Mitral regurgitation can be seen in those dysrhythmias which have longer cycle lengths. One of these dysrhythmias is the variable rhythm of atrial fibrillation. Because of the prolongation that can occur between heart beats, the pressure has time to equilibrate between the two chambers, allowing the "washing back and forth" phenomenon to occur.

28. By focusing on this view, the auditing cardiologist distracts from the view that forms the basis for my interpretation of moderate mitral regurgitation.

29. The two frames to which I refer occur at 09:34:33 and 09:37:50. These two views demonstrate classical mitral regurgitation and further demonstrate that the regurgitant

jet takes up at least 25% of the left atrium size.

The Trust then issued a final post-audit determination, again denying Ms. Barber's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Barber's claim should be paid. On March 31, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6111 (Mar. 31, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 2, 2006, and claimant submitted a sur-reply on June 22, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[7] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor,

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7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Barber argues that there is a reasonable medical basis for her Dr. Notske's finding of moderate mitral regurgitation. According to claimant, Dr. Notske correctly included surrounding lower flow spray when measuring the level of claimant's mitral regurgitation, as required by Feigenbaum. In addition, claimant contends that "low velocity flow" referenced in PTO No. 2640 is different from "surrounding lower flow spray," and that Dr. Notske did not violate the standards set forth in PTO No. 2640 because he did not include

backflow, artifacts, or phantom jets in his measurement. Claimant also argues that nothing in the Weyman text or PTO No. 2640 requires the frames from which measurements are taken to be consecutive or sequential, only that they be representative. Claimant further reiterates that the auditing cardiologist and Dr. Notske relied on different frames. Finally, claimant contends that, although Dr. Brown determined claimant's level of mitral regurgitation was mild, that finding "is common in [Dr. Notske's] experience for a clinical cardiologist to find the severity of a regurgitant mitral valve as 'mild' or 'mild to moderate' when the severity of the mitral regurgitation is moderate based upon the Singh criteria of an RJA/LAA of 20% or greater."

In response, the Trust argues that claimant has failed to establish a reasonable medical basis for her claim because she did not and cannot identify a sustained, representative high velocity jet of mitral regurgitation. The Trust further contends that claimant's citation to Feigenbaum is "misguided" and that "when read in context Feigenbaum does not, as Dr. Notske and [claimant] would have it, require that low velocity flow be included when measuring mitral regurgitant jets." According to the Trust, if Dr. Notske did include lower flow spray in his review of claimant's mitral regurgitation, "he failed to follow the instructions in PTO [No.] 2640 and PTO [No.] 6339 and his opinion is beyond the bounds of medical reason." It also argues that Dr. Notske did not review multiple loops that were

consecutive and that claimant cannot rely on only the maximum jet. Finally, the Trust contends that claimant "does not dispute Dr. Brown's finding of 'mild mitral regurgitation' and therefore, apparently admits that, utilizing normal clinical standards, she has only mild mitral regurgitation."

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and stated that she was unable to determine whether claimant had moderate mitral regurgitation. Specifically, Dr. Abramson observed:

> I obtained this very limited echocardiogram in a CD format. There were only thirty-three clips in the entire study; only three of these clips pertained to the assessment of mitral regurgitation. There was only one cardiac cycle with color flow imaging in each of the standard apical views- one apical-4-chamber, one apical-2-chamber and one apical-long axis. Since my assessment should be based on representative cardiac cycles, it is difficult to assume that these three cardiac cycles are representative cycles.
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> However, I did the measurements on these three cardiac cycles. In the apical-4-chamber (9:34:42), I measured a RJA/LAA of 3.4 cm^2/14.8 cm^2. In the apical-2-chamber (9:37:50), I measured a RJA/LAA of 4.5 cm^2/17.5 cm^2. In the apical-long axis (9:39:32), I measured a RJA/LAA of 2.4 cm^2/19.1 cm^2. Two of these ratios are greater than 20% and one ratio is less than 20%.
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> ....
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> In summary, this is an extremely limited echocardiographic study. Two of the three cardiac cycles that I found on this CD showed an RJA/LAA ratio greater than 20%, but I cannot determine if these cardiac cycles are representative of claimant's true level of

> regurgitation. Therefore, I am unable to determine whether claimant suffers from moderate mitral regurgitation.

In response to the Technical Advisor Report, claimant argues that the Technical Advisor confirmed the attesting physician's conclusion that Ms. Barber's echocardiogram demonstrates moderate mitral regurgitation. According to claimant, the echocardiogram she submitted satisfies the requirements of the Settlement Agreement. In addition, claimant notes that Dr. Abramson is the only physician to find the echocardiogram limited and that she did not identify any breach of the Feigenbaum or Weyman protocols.

After reviewing the entire show cause record, we find claimant's arguments without merit. We disagree with claimant that her attesting physician's declaration establishes a reasonable medical basis for her claim. We are required to apply the standards delineated in the Settlement Agreement and Audit Rules. The context of those two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include, among other things, failing to review multiple loops and still frames and failing to examine the regurgitant jet throughout a portion of systole. See PTO No. 2640 at 9-15 (Nov. 14, 2002).

We also have rejected attempts by claimants to rely on still frame images documented on the echocardiogram tape that were not representative of the level of mitral regurgitation

present on the particular study. See, e.g., PTO No. 8659 at 10 (Aug. 8, 2011). As we explained, "'[f]or a reasonable medical basis to exist, a claimant must establish that the findings of the requisite level of regurgitation are representative of the level of regurgitation throughout an echocardiogram.'" Id. (quoting PTO No. 6997 at 11 (Feb. 26, 2007)); see also In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Products Liab. Litig., 543 F.3d 179, 187 (3d Cir. 2008). "'To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement.'" Id. (quoting PTO No. 6997 at 11).

Ms. Barber, in response to the Technical Advisor Report, did not dispute that the frames Dr. Notske identified may not be representative of the level of mitral regurgitation throughout the echocardiogram. Instead, she relied on her interpretation of the Feigenbaum and Weyman texts that she may establish the requisite level of regurgitation merely by referencing at least one instance where the RJA/LAA ratio exceeds 20%. This contention is inconsistent with the Settlement Agreement and our prior holdings interpreting the Settlement Agreement.[8]

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8. It appears Dr. Notske included "lower flow spray" in reaching his conclusion that claimant's echocardiogram demonstrated moderate mitral regurgitation. We repeatedly have held that the inclusion of "lower flow spray," or low velocity flow, constitutes conduct beyond the bounds of medical reason for

(continued...)

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Barber's claim for Matrix A benefits and the related derivative claim submitted by her spouse.

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8. (...continued)
purposes of the Settlement Agreement. See, e.g., PTO No. 8598 at 8-11 (Feb. 8, 2011).